UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Renée Marie Bumb Chief District Court Judge
This Document Relates to the TPP Trial Claims	

TPP TRIAL DEFENDANTS'MEMORANDUMIN SUPPORT OF MOTION FOR SUMMARY JUDGMENT[1]

[1] This Motion for Summary Judgment concerns the claims designated in Case Management Order No. 32 (the "TPP Trial Claims"), specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC, as class representative of TPP Breach of Express Warranty subclass b, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a (collectively, the "TPP Classes"), against the TPP Trial Defendants. (ECF 2343 at 1-2.) Defendants were previously granted summary judgment on the claims asserted by Implied Warranty subclass d. (ECF 2695 at 5.) In filing this motion, Defendants do not waive any arguments in favor of summary judgment with respect to any other claims asserted by any Plaintiff as to any Defendant(s) in this multidistrict litigation.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (CONT'D)

Page

TABLE OF AUTHORITIES (CONT'D)

Page

Statutes

INTRODUCTION

The Third-Party Payor Plaintiffs ("Plaintiffs") have alleged throughout this litigation that they are entitled to a full refund of the amounts they paid for life-saving valsartan-containing drugs that contained N-Nitrosodimethylamine ("NDMA") and/or N-Nitrosodiethylamine ("NDEA") (the "VCDs"), because the medications were entirely "worthless." "[I]t is one thing to allege damages," however, "and it is another thing to prove damages." *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875, 2025 WL 1024048, at *6 (D.N.J. Apr. 7, 2025). In an effort to prove their theory, Plaintiffs designated Dr. Rena Conti as an expert witness to testify that the VCDs had no value. Because the Court excluded Dr. Conti's "worthlessness" opinion as "unreliable," *id.* at *19-20, Plaintiffs do not have admissible expert testimony capable of proving their claims.

Defendants are entitled to summary judgment for multiple reasons.

First, the exclusion of Dr. Conti's "worthlessness" opinion leaves Plaintiffs without evidence capable of proving that the VCDs had no value. This Court has ruled that establishing "worthlessness" at trial requires expert evidence that the "VCDs were so fundamentally flawed so as to be rendered valueless." *In re Valsartan*, 2025 WL 1024048, at *17. Plaintiffs' own counsel have unequivocally conceded that Plaintiffs lack such evidence because their remaining experts "don't address value of the pills" and "are not going to say [the VCDs contain] a

fundamental defect." (Apr. 28, 2025 Hr'g Tr. ("April CMC Tr.") 28:18, 31:5-6, ECF 3039.) Plaintiffs' counsel have also acknowledged that their general causation experts cannot quantify any loss of value to the VCDs based on the relevant epidemiologic studies, which have: (1) found no increased risk of cancer generally for patients exposed to the VCDs; and (2) at most, inconsistently reported slightly increased risks for a few specific cancers. This is not a curable evidentiary gap. Courts routinely grant summary judgment where plaintiffs lack expert testimony to establish product worthlessness or diminished value in complex pharmaceutical cases. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (rejecting worthlessness theory absent expert support); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, 2023 WL 4765409, at *8 (S.D. Fla. July 26, 2023) (same).

Second, Plaintiffs cannot salvage their claims by redefining their theory of damages at this late stage of the proceedings. Although Plaintiffs initially (and alternatively) pled that the VCDs were "worth less" than what Plaintiffs paid for them, Judge Kugler dismissed this theory of liability because Plaintiffs "fail[ed] to allege facts which would permit a factfinder to value the purported injury with[out] resorting to mere conjecture." (MTD Op. 2 at 11, ECF 728.) Plaintiffs never moved

to amend their complaint to reassert that dismissed theory;[2] instead, they doubled down on their "worthlessness" theory to facilitate class certification because it avoided "individualized issues regarding the value [of the VCDs] to each Class Member[.]" (*See* Pls.' Consumer Economic Loss Class Cert. Br. at 79, ECF 1748.)

In any event, even if Plaintiffs had not abandoned a "worth less" theory, they lack any expert evidence capable of proving damages under that theory, which is why they recently requested permission to reopen discovery and designate new experts. The Court made clear that it "definitely" will not entertain Plaintiffs' dilatory request given the advanced stage of these proceedings (April CMC Tr. 46:23-47:23), and there is no legitimate basis to reconsider that decision, as set forth in the TPP Trial Defendants' Opposition to Plaintiffs' Motion for Leave to Reopen Expert Record ("TPP Defs.' Reopening Opp'n") (ECF 3080), which is currently pending before the Court.

Third, Plaintiffs' claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, which holds that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the

[2] It was not until Plaintiffs' November 12, 2024, letter to the Court that they asked this Court in a footnote to allow them to amend their complaint "to more explicitly add a worth less theory[.]" (ECF 2921 at 23 n.19.) The Court's April 7, 2025 Opinion addressed Plaintiffs' request, ruling amendment was not needed. (ECF 3018 at 48.)

Administration's judgment and objectives." 531 U.S. 341, 350 (2001). Although Judge Kugler rejected this argument at the pleading stage based on inapposite precedent, the evidence that Plaintiffs have since developed to support their claims (e.g., that Defendants allegedly withheld information about VCDs from the FDA) confirms that they are attempting to proceed with an impermissible fraud-on-the-FDA theory that is preempted by federal law.

For all of these reasons, discussed in greater detail below, the Court should grant Defendants summary judgment on all of Plaintiffs' claims.

BACKGROUND

Defendants voluntarily recalled various finished-dose VCDs beginning in July 2018, after identifying trace amounts of NDMA or NDEA. (*See* Defs.' Omnibus Statement of Material Facts Not in Dispute ("Orig. SUMF") ¶¶ 77-78, ECF 2571.)[3] There is no evidence that any of the VCDs failed to provide effective blood pressure treatment to the patients who purchased and used them. (*Id.* ¶ 80.) The FDA stated after the recall that "[t]he risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine[.]" (*Id.* ¶ 82.) Specifically, the FDA estimated that, "if 8,000 people took the highest valsartan dose (320 mg) from

[3] The TPP Trial Defendants incorporate herein the original statement of undisputed material facts supporting their motion for summary judgment filed last year, as well as a supplemental statement of undisputed material facts.

NDMA-affected medicines daily for four years (the amount of time we believed the affected products had been on the U.S. market), there may be one additional case of cancer over the lifetimes of these 8,000 people beyond the average cancer rate among Americans," and that "[m]ost patients who were exposed to the impurity through the use of valsartan received less exposure than this worst-case scenario." (*Id.* ¶ 78.) Thus, the FDA recommended that patients "should continue taking their medicine until they have a replacement product." (*Id.* ¶ 81.)

No epidemiologic study has found that exposure to VCDs containing NDEA is associated with an increased risk of cancer. (Supp. Statement of Material Facts Not in Dispute ("Supp. SUMF") ¶ 4.) Only three epidemiologic studies have assessed whether there is an association between the use of VCDs containing NDMA and an increased risk of cancer, and none of those studies identified an overall increased risk. The first study, Pottegard 2018, found that "[o]verall, exposure to potentially (probably or possibly) NDMA contaminated valsartan products showed ***no association with cancer*** compared with exposure to valsartan products" that did not contain NDMA, with "***no evidence*** of a dose-response relation," further weighing against any causal link. (*Id*. ¶ 6 (emphases added).) Although the study noted that "increased risks were seen for colorectal cancer . . . and for uterine cancer," "neither these nor other single cancer outcomes reached statistical significance[.]" (*Id*.) The second study, Gomm 2021, similarly found no association

with cancer overall and only a small association for liver cancer. (*Id.* ¶ 7.) The study authors observed a lack of a dose-response, including for liver cancer, and emphasized that "***[c]ausality cannot be inferred***." (*Id.* (emphasis added).) The third and last study, Mansouri 2022, reported "no increased risk of overall cancer among exposed patients" and only "found a slightly increased risk" for liver cancer and melanoma, which the study authors noted may be explained by confounding factors. (*Id.* ¶ 8.) The study authors further concluded that they "found no evidence of a dose-response relationship[.]" (*Id.*)

Despite the extremely low risk (if any) of cancer and the undisputed efficacy of the VCDs in treating hypertension, Plaintiffs have alleged from the inception of this litigation that the contamination rendered the VCDs "worthless." Although the Second Amended Complaint ("SAC") also asserted that the VCDs had "significantly diminished . . . value" (SAC ¶¶ 454, 465, 474, ECF 398), Plaintiffs' opposition to Defendants' motion to dismiss (filed in September 2020) made clear that Plaintiffs were proceeding solely on the theory that the TPPs "were economically injured by paying for a worthless drug," and offered no plausible facts to measure the VCDs' "diminished" value (ECF 577 at 24). Judge Kugler dismissed any claims based on a theory that VCDs had diminished value on the ground that Plaintiffs had "fail[ed] to allege facts which would permit a factfinder to value the purported injury with[out] resorting to mere conjecture." (MTD Op. 2 at 11, ECF 728.)

At class certification, Plaintiffs continued to assert that their sole theory of injury rested on "Dr. Conti's damages" theory, arguing that their "worthlessness" theory supported class certification because the value was $0 for all class members, rendering any "individualized issues regarding the value to each Class Member of the VCDs" moot. (ECF 1748 at 79.) Judge Kugler accepted Plaintiffs' proposition, certifying a TPP class based on the core allegation that the "VCDs were worthless" and on Plaintiffs' demand for "the full cost of their payments for their insureds' VCDs over the relevant period." (ECF 2261 at 36.) And when Defendants moved for summary judgment in 2024, Plaintiff MSP Recovery Claims (the named plaintiff for the TPP class trial) once again confirmed that its only theory of damages was the one advanced by Dr. Conti: namely, that the VCDs were "'worthless'" (ECF 2569-1 at 33 (arguing that "[Judge Kugler] has already determined . . . that the VCDs are 'economically worthless'") (citing ECF 775 at 20)).[4]

Defendants moved to exclude Dr. Conti's opinions in advance of the previously scheduled TPP class trial. Briefing on that motion was completed on March 6, 2024, but Judge Kugler did not rule on the motion prior to his retirement and the subsequent reassignment of the MDL proceeding to this Court. On

[4] Judge Kugler subsequently rejected all claims asserted by Implied Warranty subclass d, as well as consumer-protection claims asserted under Missouri law, but allowed Plaintiffs to proceed with the remaining claims set for a TPP class trial. (*See* ECF 2695.)

September 9, 2024, this Court heard argument on the admissibility of Dr. Conti's opinions, and on April 7, 2025, the Court ruled that it "will not permit Conti to testify that the VCDs are worthless." *In re Valsartan*, 2025 WL 1024048, at *19. The Court subsequently granted Defendants' request to move for summary judgment on the TPP class claims. (April CMC Tr. 18:20-19:1.)

ARGUMENT

A defendant is entitled to summary judgment when a plaintiff "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[A] mere 'scintilla of evidence' in the nonmovant's favor does not create a genuine issue of fact[.]" *Ramara, Inc. v. Westfield Ins. Co.*, 814 F.3d 660, 666 (3d Cir. 2016). Rather, the plaintiff "must introduce evidence from which a rational finder of fact could find in [his or her] favor." *Colburn v. Upper Darby Twp.*, 946 F.2d 1017, 1020 (3d Cir. 1991).

Defendants are entitled to summary judgment because: (1) Plaintiffs cannot prove injury or damages; and (2) Plaintiffs' claims are separately preempted.

I. PLAINTIFFS CANNOT PROVE INJURY OR DAMAGES.

A. Plaintiffs Cannot Establish Injury Or Damages On The Theory That The VCDs Were "Worthless."

The TPP Trial classes assert three categories of claims: (1) breach of express warranty; (2) common law fraud; and (3) state consumer protection.[5] *See In re Valsartan*, 2025 WL 1024048, at *1-2. This Court has already determined that "the correct measure of damages for the breach of express warranty claim is the difference in value between what was bargained for and what was received, known as the benefit of the bargain theory." *Id.* at *4 (citation omitted). To prove damages under that standard, Plaintiffs must establish either that:

(1) there was such a fundamental defect in the VCDs that so outweighed their undisputed lifesaving benefits that the drugs were "worthless"; or

(2) the risk posed by the defect diminished the value of the medications such that they were "worth less."

[5] Judge Kugler ruled that Plaintiffs' claims are governed by "the law[s] of [their] home state[s]"—i.e., where each TPP is located. (ECF 818 at 10.) Yet, each of the TPP subclass definitions is limited to specific states in which TPP subclass members "paid any amount of money" for VCDs, which may or may not be their home states. (ECF 2532-6.) This disconnect between the states whose laws govern (i.e., each TPP's home state) and the states encompassed by the subclass definitions (i.e., the state where each TPP paid for valsartan) makes it impossible to discern what law governs each unnamed subclass member's claims. For present purposes, however, this motion assumes—without conceding—that the claims at issue are governed by the 42 jurisdictions identified across the three subclasses selected for trial.

Id. (*See also* April CMC Tr. 18:20-19:1.) That same framework applies to Plaintiffs' common law fraud claims and state consumer protection claims.

Common Law Fraud. Of the 23 jurisdictions at issue, 20 have expressly adopted either a benefit-of-the-bargain theory or an "out of pocket" measure of damages.[6] As discussed above, the Court has already determined that a benefit-of-the-bargain theory requires TPP Plaintiffs to prove that the VCDs were "worthless" or "worth less." *In re Valsartan*, 2025 WL 1024048, at *8. The same is true for an "out-of-pocket" theory, which measures "the difference between the price paid for the [product] and the [product's] actual value when received." *See, e.g.*, *Wallis v. Ford Motor Co.*, 208 S.W.3d 153, 155 (Ark. 2005); *Walston v. Monumental Life Ins. Co.*, 923 P.2d 456, 462 (Idaho 1996) (similar). Thus, "[e]ither measure of damages requires a plaintiff to prove the actual value of the [good] at the time of purchase," *Kind v. Gittman*, 889 So. 2d 87, 90 (Fla. Dist. Ct. App. 2004), as Plaintiffs themselves have essentially recognized (*see* MSP Summ. J. Opp'n Br. at 39, ECF 2606 (stating in prior summary judgment opposition that "the general approach is the same under either" a benefit-of-the-bargain or out-of-pocket theory)).

[6] Benefit-of-the-bargain jurisdictions include Colorado, Massachusetts, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, and Washington. (*See* Ex. A to Ltr. from C. Trischler, ECF 3035-1.) Out-of-pocket jurisdictions include New York, Virginia, and Puerto Rico. (*Id.*) Jurisdictions that use both benefit-of-the-bargain and out-of-pocket approaches include Alaska, Arkansas, Florida, Idaho, Iowa, Minnesota, and Wyoming. (*Id.*)

As to the remaining three jurisdictions (New Jersey, the District of Columbia, and Louisiana), New Jersey uses either a benefit-of-the-bargain or out-of-pocket approach, "subordinate[] to the basic objective of making the injured party whole." *See Correa v. Maggiore*, 482 A.2d 192, 198 (N.J. Super. Ct. App. Div. 1984). Under this standard, Plaintiffs must still prove the actual value of the VCDs. New Jersey "mak[es] the injured party whole" by measuring damages as the "diminution in value caused by defendants' deceit[.]" *Id.* The District of Columbia and Louisiana have not expressly formulated a measure of damages for fraud, but courts in both jurisdictions have similarly looked to the actual value of the product. *See Railan v. Katyal*, 766 A.2d 998, 1006 n.7 (D.C. 2001) (measure of damages includes "the difference between the value of the property and the price paid for it"); *Gagliano v. Namias*, 479 So. 2d 23, 25 (La. Ct. App. 1985) (similar).[7]

[7] Plaintiffs have at times suggested that a separate measure of damages may apply to fraud claims, analogizing this case to the sale of "snake oil" as medicine. Even if such a standard ever applied to fraud claims, it would plainly not apply to "the facts of this case" because, as this Court made clear, "these drugs were, in fact, sold and did, in fact, provide a therapeutic value"—i.e., they were not "snake oil." *See In re Valsartan*, 2025 WL 1024048, at *15 n.24 ("Conti ignores the facts of this case, that is, that these drugs were, in fact, sold and did, in fact, provide a therapeutic value."). Moreover, Plaintiffs lack evidence that ZHP engaged in any knowing or intentional misrepresentations, as required under the applicable states' fraud laws. (*See* ZHP Mot. for Summ. J. at 1, 7-10, ECF 2564-1.) And as to Defendants Teva and Torrent, there is no evidence indicating that either had knowledge of the existence of an impurity in the active pharmaceutical ingredient for its VCDs. (*See* Teva's Mot. for Summ. J. at 6-8, ECF 2565-1; Torrent's Mot. for Summ. J. at 3-7, ECF 2750-1.)

State Consumer Protection Laws. All 16 jurisdictions at issue require Plaintiffs to prove an "ascertainable loss" or "actual damages." *See, e.g.*, Conn. Gen. Stat. § 42-110g(a) ("Any person who suffers any ascertainable loss . . . may bring an action . . . to recover actual damages."). (*See also* Ex. B to Ltr. from C. Trischler, ECF 3035-2.) Thus, Plaintiffs must present evidence that "the seller's misrepresentations rendered the product essentially worthless" (or that the product was worth less than paid). *See In re Cheerios Mktg. & Sales Pracs. Litig.*, MDL No. 2094, 2012 WL 3952069, at *11 (D.N.J. Sept. 10, 2012). Consistent with this requirement, courts in at least five of the relevant jurisdictions (Alaska, California, Florida, Louisiana, and Pennsylvania) expressly consider the actual value received or benefits conferred. *See, e.g.*, *Borgen v. A & M Motors, Inc.*, 273 P.3d 575, 592 (Alaska 2012); *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 131 (2009); *Rollins, Inc. v. Heller*, 454 So. 2d 580, 585 (Fla. Dist. Ct. App. 1984); *Harris v. Poche*, 930 So. 2d 165, 172 (La. Ct. App. 2006); *Stokes v. Gary Barbera Enters.*, 783 A.2d 296, 299 (Pa. Super. Ct. 2001).[8]

[8] The fact that some consumer protection statutes prescribe statutory damages does not relieve Plaintiffs of their burden to demonstrate an ascertainable loss or actual damages as an element of their underlying claim before the factfinder can consider the appropriate measure of damages. And even as a measure of damages, the statutes typically require a comparison of the actual value to statutory damages. *See, e.g.*, Alaska Stat. § 45.50.531(a) ("A person who suffers an ***ascertainable loss*** of money or property . . . may bring a civil action to recover for each unlawful act or practice ***three times the actual damages*** or $500, whichever is greater.") (emphases added). Recovery under these statutes thus requires both ascertainability

In short, Plaintiffs' claims for breach of express warranty, common law fraud, and violation of state consumer protection laws all require evidence that the VCDs were either "worthless" or "worth less" than what the TPPs paid or bargained for. Because Plaintiffs have no such evidence, as discussed below, Defendants are entitled to summary judgment. *See Willoughby v. Abbott Labs.*, No. 22 C 1322, 2025 WL 622925, at *7 (N.D. Ill. Feb. 26, 2025) ("Without evidence of overpayment . . . the plaintiffs cannot prove the damages required for their consumer protection [and] fraud . . . claims.").

This Court has already rejected Plaintiffs' theory that the VCDs were "worthless" and that Plaintiffs are thus entitled to a full refund. (*See* April CMC Tr. 18:10-19 ("The plaintiffs keep wanting to sneak back in that they are worthless—one word. And there is just simply no evidence for that. . . . I thought my Opinion was clear that that's out of the case.").) In its order excluding Dr. Conti's damages opinions, the Court made clear that Plaintiffs may only prove a "worthlessness" theory through competent expert testimony that the purported defect in the VCDs was so "fundamental that the product [was] rendered valueless." *In re Valsartan*, 2025 WL 1024048, at *8. All other avenues of establishing "worthlessness" are foreclosed by the record. *Id.*

---

of the asserted injury and proof of the "actual damages" allegedly sustained, which necessarily entails consideration of the value of the VCDs to each TPP.

As the Court recognized, "Plaintiffs' only evidence to support worthlessness . . . is Conti's [now-excluded] testimony." *Id.* at *17. Plaintiffs' counsel subsequently admitted at the April Case Management Conference that their remaining experts "don't address value of the pills" and that those experts "***are not going to say it's a fundamental defect***." (April CMC Tr. 28:18, 31:5-6; *id.* 29:25-30:2 (emphasis added).) Plaintiffs' admission is dispositive. *See In re Valsartan*, 2025 WL 1024048, at *17 ("Plaintiffs cannot simply assert a fundamental flaw; they must prove it."). (*See also* April CMC Tr. 31:1-3 ("There's got to be—either the testimony is going to be that . . . it was such a fundamental defect or—I don't know how that's going to be helpful to a jury.").)

To the extent Plaintiffs' remaining experts testify about the alleged risk of VCDs based on epidemiologic studies, Plaintiffs have conceded that their opinions will not and cannot address or quantify any diminished value of the pills. (April CMC Tr. 28:18, 31:5-6; *see also* § I.B.2 *infra* (citing admissions by Plaintiffs' counsel that they lack evidence of an "economic translation" of general causation opinions into value opinions based on benefits and risks).) Further, the epidemiologic studies do not remotely purport to establish "worthlessness." None of Plaintiffs' experts can point to any epidemiologic evidence that the use of VCDs containing NDEA is associated with an increased risk of any cancer. And as noted above, although three studies have assessed whether the use of VCDs containing

NDMA is associated with cancer, none found a statistically significant increase in risk for cancers overall. (*See* Supp. SUMF ¶¶ 5-8.)

The record evidence further reflects that the presence of NDMA or NDEA in VCDs indisputably did not render the medications worthless.[9] Most notably, the FDA stated at the time of the recall in 2018: "Because valsartan is used in medicines to treat serious medical conditions, ***patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product***." (Orig. SUMF ¶ 81 (emphasis added).) The FDA's own risk assessment is dispositive: "The risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine[.]" (*Id.* ¶ 82.) The FDA estimated that, "if 8,000 people took the highest valsartan dose (320 mg) from NDMA-affected medicines daily for four years (the amount of time we believed the affected products had been on the U.S. market), there may be one additional case of cancer over the lifetimes of these 8,000 people beyond the average cancer rate among Americans . . . ." (*Id.* ¶ 78.) Plaintiffs cannot establish that the VCDs were fundamentally

[9] Defendants' experts Michael Bottorff and Dr. John Flack explained that the presence of NDMA impurities did not impact the efficacy of the VCDs. (Orig. SUMF ¶ 125.) Plaintiffs did not produce any expert to rebut their effectiveness opinions. (*Id.* ¶ 79.) To the contrary, Plaintiffs' expert Dr. Rena Conti admitted that she could not identify any scientific evidence indicating that the VCDs were ineffective in treating hypertension. (*Id.*)

defective (and worthless) when the FDA advised patients to continue taking them even after the recall because of their important benefits and extremely low risk. (*Id.* ¶ 81.) *See In re Rezulin*, 210 F.R.D. at 68-69 (holding that plaintiffs' worthlessness theory was "not a defensible position" because "[e]ven plaintiffs' experts acknowledge that [the product] was enormously beneficial to many patients"); *In re Zantac*, 2023 WL 4765409, at *8 ("Plaintiffs lack any basis . . . to advance the proposition that ranitidine is worthless, with a value of zero, even though it performed as advertised[.]").

As the Court has already recognized, "there is just simply no evidence" in the record to support Plaintiffs' theory that the VCDs were worthless. (April CMC Tr. 18:10-16; *see id.* ("I'm not going to permit any expert to say 'this is full damages.'").) Rather, Plaintiffs' "worthlessness" theory is "out of the case . . . because everyone agrees that these drugs had a value." (*Id.*)

B. Plaintiffs Cannot Establish Injury Or Damages On The Theory That The VCDs Were "Worth Less."

Plaintiffs also cannot proceed to, or prevail at, trial on an alternative theory that the VCDs were "worth less" than what Plaintiffs paid for them. As this Court has recognized and as Plaintiffs themselves have admitted in seeking to re-open expert discovery, such a "worth less" theory requires Plaintiffs to establish the economic value of the VCDs considering the alleged risk and then calculate the difference between that value and the price the Plaintiffs paid for the VCDs. (*See*

April CMC Tr. 41:10-13, 43:7-9; *see also* Pls.' Mot. for Leave to Reopen Expert Record at 2, ECF 3053.) Such a theory is not viable because: (1) those claims were rejected by Judge Kugler on the pleadings and abandoned by Plaintiffs to pursue class certification; and (2) Plaintiffs lack evidence that would allow the jury to value the VCDs, and thus to find that the VCDs were worth less than what Plaintiffs paid (or bargained) for them.

1. Plaintiffs Have Abandoned The "Worth Less" Theory.

At the pleading stage of this case, Plaintiffs attempted to allege injury-in-fact and damages by asserting, among other theories, that the value of the VCDs was significantly diminished:

> As a direct and proximate result of each TPP Claim Defendant's [course of action], Plaintiffs and other Class Members have been injured and suffered damages, in that TPP Claim Defendants' VCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have ***significantly diminished*** or no intrinsic market value.

(SAC ¶¶ 454, 465, 474 (emphasis added); *see also* Consolidated Am. Economic Loss Class Action Compl. ("FAC") ¶¶ 445, 456, 465, ECF 121.) Plaintiffs also alleged elsewhere in their pleadings that, "[a]t a minimum, adulterated, misbranded, and/or unapproved VCDs were ***worth less*** than their non-contaminated equivalents." (SAC ¶ 371; FAC ¶ 362 (emphasis added).)

Plaintiffs quickly abandoned their "worth less" theory in their opposition to Defendants' motion to dismiss, insisting that they were harmed solely because

"VCDs are worthless to Plaintiffs," while citing no factual allegations plausibly supporting their "diminished value" theory. (*See, e.g.*, ECF 577 at 26.) Accordingly, Judge Kugler held that the "worth less" theory was insufficiently pled.

> The second theory of economic loss, the receipt of a less valuable product, would have sufficed to establish an injury-in-fact if Plaintiffs had provided a theory for the factfinder to value it, but they do not. Instead, they would have the factfinder resort to mere conjecture to value their purported injury. This second theory is insufficient to confer standing.

(MTD Op. 2 at 13, ECF 728.) In other words, Judge Kugler identified the exact same problem with Plaintiffs' "worth less" theory that this Court recently elucidated: Plaintiffs have not identified a basis for the jury to value the VCDs. (*See* April CMC Tr. 41:6-9 ("So to have experts testify, well, there's a risk of cancer . . . and the jury is just supposed to just say just—what? I mean, make up a number . . . ? No."); *see also* MTD Op. 2 at 13, ECF 728 (Judge Kugler explaining that, for a "worth less" theory to be viable, Plaintiffs must provide a basis "for the factfinder to value [the VCDs]").)

Plaintiffs cannot now switch horses and proceed on a "worth less" theory for at least two reasons.

First, Plaintiffs never timely moved to re-introduce their "worth less" theory, much less attempted to remedy the core deficiency identified by Judge Kugler. Plaintiffs had the opportunity to do so when they filed a Third Amended Complaint, which added 89 pages of new allegations to address Judge Kugler's various motion-

to-dismiss rulings, including additional allegations about "worthlessness." (*See generally* Third Am. Compl. ("TAC"), ECF 1708.) Yet, the TAC did not include a single new allegation to fortify the "diminished value" theory. Accordingly, they cannot pursue it now. *See Krys v. Aaron*, 312 F.R.D. 373, 377 (D.N.J. 2015) ("[f]ailure to raise any claims, issues, defenses, or theories of damages . . . generally results in waiver") (citation omitted); *see also In re Zantac*, 2023 WL 4765409, at *8 (holding that the "[p]laintiffs abandoned the contention that ranitidine is worth less" where plaintiffs had previously "represented to the Court that" the medication did ***not*** "have a value greater than zero" and insisted that "[w]e are talking about a drug that was recalled because it causes cancer" and is therefore "worthless").

Second, Plaintiffs cannot pursue a "worth less" theory at this late stage because their entire argument in support of class certification was based on the now-rejected "worthless" theory of injury. Plaintiffs affirmatively argued at class certification that they could prove the value of the VCDs on a class-wide basis by establishing that the VCDs should never have been sold and thus had zero value to each and every class member. (*See* Pls.' Class Certification Reply Br. at 17, ECF 2057 (relying on Dr. Conti's testimony to argue that "the purported 'therapeutic value' received by each class member is irrelevant because all class members . . . purchased an economically worthless drug"). Plaintiffs never proposed a means to prove on a class-wide basis that the VCDs were "worth less" or to measure the

diminished value of VCDs—intentionally so because such individualized inquiries are fundamentally incompatible with classwide litigation. If Plaintiffs were to proceed now with a different theory that VCDs were "worth less" to patients than what Plaintiffs paid for them, class certification would need to be re-briefed and argued so that the Court could determine—for the first time—whether such a theory could be proven on a class-wide basis using common evidence. *See, e.g.*, *Lanteri v. Credit Prot. Ass'n, L.P.*, No. 1:13-CV-01501-JMS-MJD, 2020 WL 3200076, at *3 (S.D. Ind. June 15, 2020) (rejecting plaintiffs' attempt to change their theory of liability after class certification; "the Class is not permitted to proceed on any alternative theory of liability other than the one for which the Class was certified").

Reassessing class certification would be essential here given that the Third Circuit and other courts have frequently rejected certification of claims based on a theory that a product was "worth less." As these courts have recognized, such theories cannot satisfy Rule 23's predominance requirement because they require individualized inquiries regarding the actual value of the product to each purchaser in light of his or her particular circumstances. *See, e.g.*, *Maio v. Aetna, Inc.*, 221 F.3d 472, 493 (3d Cir. 2000) (plaintiffs "obviously cannot show that they actually received something 'inferior' and 'worth less' absent individualized allegations"); *Alvarez v. NBTY, Inc.*, 331 F.R.D. 416, 426 (S.D. Cal. 2019) (denying class certification because "under Plaintiff's theory, some people benefitted from the

Products," and thus, "damages are not subject to common proof on a class-wide basis").

2. Plaintiffs Lack Admissible Evidence Capable Of Establishing That The VCDs Were "Worth Less."

Even if Plaintiffs were permitted to resurrect their "worth less" theory at this late stage (and such a theory could survive Rule 23 scrutiny), their claims would not survive summary judgment. In order to prove the "worth less" theory, Plaintiffs must: (1) present expert testimony from an economist that weighs the purported causation evidence of any increased risk against the undisputed therapeutic benefits of the VCDs; and (2) "translate[]" that into a precise diminution in value. (*See* MTD Op. 2 at 13, ECF 728; April CMC Tr. 43:7-9.) Plaintiffs have no such evidence.

At the April Case Management Conference, Plaintiffs suggested that they could carry their burden by having their experts opine that there is some risk of cancer, and then ask jurors to determine whether (and, if so, to what degree) such a risk diminished the value of the VCDs. (*See* April CMC Tr. 35:22-36:7.) Both Judge Kugler and this Court have rejected that position. (*See* MTD Op. 2 at 13, ECF 728; April CMC Tr. 43:12-16.) As a result, even Plaintiffs now agree that, in order to pursue claims that VCDs were "worth less" than represented, they must produce new expert testimony translating their experts' assessment of the alleged risks posed by NDMA/NDEA in VCDs into an economic value of those VCDs. (*See* Pls.' Mot. for Leave to Reopen Expert Record at 2, ECF 3053 ("[T]he upshot of its April 7 ruling

is that TPP Plaintiffs should have an economic 'translating mechanism' to help the jury evaluate the economic impact associated with the scientific or general causation evidence about NDMA . . . on the value of the VCDs purchased.").)

Plaintiffs admittedly do not have this evidence. Plaintiffs have repeatedly conceded that they lack the economic translation evidence required to proceed on a "worth less" theory, telling the Court: "***We don't have that [evidence] in this case***." (April CMC Tr. 40:5-9 (emphasis added) (Plaintiffs' counsel stating that "[t]he jury needs to have somebody translate that, and that gets us into an economic sort of price premium model where the question is then put economically to someone to determine what impact to value or price or worth it has. We don't have that in this case."); *see id.* 41:10-14 ("[Court]: [T]here has to be an economic translation into risk and benefits, and I don't know what that economist looks like, but that's the piece that is missing. [Plaintiffs' counsel]: Yes. I agree, Your Honor.").) This is so because the only economist Plaintiffs designated was Dr. Conti, whose "overarching testimony and opinion [is] that the VCDs are worthless, *i.e.*, have no value, because they were adulterated." (ECF 3018 at 26.)

This absence of economic translation evidence is fatal to Plaintiffs' "worth less" theory. As other courts have recently held, without "evidence of how much [plaintiffs] would have paid had they known the [product] contained [the alleged defect] . . . plaintiffs cannot establish they paid more for the [product] than it was

actually worth[.]" *See Willoughby*, 2025 WL 622925, at *6-7. In *Willoughby*, the plaintiffs asserted various common law fraud and consumer protection claims based on the purchase of a purportedly defective product, alleging that they had suffered damages because "they would not have . . . paid the price they did for, the [product] if they knew about the [alleged defect]"—in other words, a "worth less" theory. *Id.* at *6. To support this theory, the plaintiffs' experts proposed a "conjoint analysis that will allow the finder of fact to quantify the price premium paid[.]" *Id*. The court nevertheless granted summary judgment because the plaintiffs' experts "have not conducted such an analysis." *Id.*

Here, none of Plaintiffs' experts has opined that there is a mechanism to determine the value of VCDs in light of the alleged risks, let alone conducted such a valuation analysis. And although Plaintiffs are again requesting that the Court allow them to re-open discovery (ECF 3053 at 2), the Court should decline to "open this all back up again" (April CMC Tr. 48:16-19; *see also id.* 46:23-47:23) for the reasons set forth in the TPP Defs.' Reopening Opp'n.[10]

For this reason, too, the TPP Defendants are entitled to summary judgment.

[10] As explained in the TPP Defs.' Reopening Opp'n (*see* ECF 3080), incorporated herein, Plaintiffs lack good cause to reopen discovery and disclose new experts at this late stage of the proceedings—and doing so would substantially prejudice Defendants.

II. PLAINTIFFS' CLAIMS ARE SEPARATELY PREEMPTED.

The Court should grant summary judgment in favor of the TPP Trial Defendants for the additional reason that Plaintiffs are inappropriately pursuing fraud-on-the-FDA claims that are impliedly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See Buckman*, 531 U.S. 341. Under the FDCA, a drug cannot be marketed without FDA approval, 21 U.S.C. § 355(a); the FDA will only approve a drug if it finds that the proposed labeling is not "false or misleading in any particular," *id.*; only the FDA may deem a drug to be "misbranded," *id.* § 352(j); and the statute's requirements may only be enforced by the federal government, *id.* § 337(a).

In *Buckman*, the plaintiffs claimed that the defendants had "made fraudulent representations to the FDA as to the intended use of the [medical device] and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment." 531 U.S. at 347. The Supreme Court rejected these claims, holding that they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. As the Court explained, the FDA uses its authority "to achieve a somewhat delicate balance of statutory objectives [that] can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348. Thus, plaintiffs' "fraud-on-the-agency claims"—which "exist[ed] solely by virtue of the FDCA

disclosure requirements" and relied on FDCA requirements as "a critical element" of their lawsuit—were preempted. *Id.* at 353.

Although *Buckman* involved state law tort claims alleging that the defendants directly misled the FDA or otherwise violated the FDCA, the Supreme Court's holding applies equally to claims that Defendants' representations to the public were false ***because*** Defendants misled the FDA or otherwise violated the FDCA. *See Atkinson v. Luitpold Pharms., Inc.*, 448 F. Supp. 3d 441, 447-48 (E.D. Pa. 2020) ("[S]tate law causes of action that are contingent upon the defendant making fraudulent representations to the FDA conflict with federal law and are, accordingly, preempted."). Such indirect fraud-on-the-FDA claims depend on an assertion that a defendant violated some requirement of the FDCA and therefore intrude upon the police power of the FDA to enforce that federal statute. *See, e.g., Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 412 (D. Del. 2014) ("While [the alleged] conduct . . . might violate the FDCA, such conduct would not exist apart from the FDCA."); *Markland v. Insys Therapeutics*, 758 F. App'x 777, 779-80 (11th Cir. 2018) ("As with the *Buckman* plaintiffs, Markland seeks to enforce a duty that exist[s] solely by virtue of the FDCA. . . . That kind of claim is preempted.") (citation omitted); *Perez v. Nidek Co.*, 711 F.3d 1109, 1112, 1119 (9th Cir. 2013) ("Perez's fraud by omission claim exist[s] solely by virtue of the FDCA . . .

requirements . . . with respect to approved use of the Laser" and is preempted) (citation omitted).

At the pleading stage, Judge Kugler analogized this case to *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Supreme Court held that the FDCA does not preempt state law tort claims against manufacturers of branded medications seeking to require additional warnings on product labels. *Id.* at 568-73. *Levine* is inapposite because it did not address a claim of implied preemption under *Buckman* based on allegations of fraud on the FDA—a fact that the majority expressly highlighted in its ruling. *See id.* at 563, 565 n.3 ("The dissent's reliance on *Buckman* . . . is especially curious, as that case involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply.") (citing *Buckman*, 531 U.S. at 347-48). Rather, *Levine* (which addressed impossibility and obstacle preemption) merely "preserves common law state tort claims that parallel or reinforce the agency's efforts but do not involve the relationship between the federal regulator and the regulated entity, the dispositive factor for federal preemption in *Buckman*." *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 377 (5th Cir. 2012); *see Romero v. Wyeth LLC*, No. 1:03-cv-1367, 2012 WL 12547105, at *6 (E.D. Tex. May 30, 2012) (similar); *Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 345 n.6 (D.N.J. 2021)

(distinguishing between fraud-on-the-FDA claims (*Buckman*) and claims that warnings should have been stronger (*Levine*)).

Even at the pleading stage, the crux of Plaintiffs' case was that "Defendants expressly warranted that their products were the same as their [Reference Listed Drugs, or] RLDs," as is required under the FDCA. (TAC ¶ 622.) Plaintiffs alleged that this warranty was false because the VCDs purportedly contained NDMA/NDEA, rendering them different from the RLDs. (*Id.*; *see also id.* ¶ 623 (alleging that Defendants misrepresented that the VCDs were "compliant with cGMP and not contaminated, adulterated or misbranded").) And in so alleging, Plaintiffs expressly and repeatedly claimed that the FDA approved the VCDs "based upon [those alleged] representations" under the federal standards. (*See, e.g.*, *id.* ¶¶ 205-06 ("The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria and were equivalent to the [reference listed drug]."); *id.* ¶ 399 (omissions).)

The record developed in the years since Judge Kugler's decision confirms beyond dispute that Plaintiffs are attempting to enforce the FDCA. (*See, e.g.*, MSP Summary J. Opp'n Br. at 18, ECF 2606 (Plaintiffs claiming that "the representations at issue (FDA approval, DMF and ANDA compliance, USP compliance, and AB rating in the Orange Book) are required in order to permit the sale of the VCDs at every step of the stream of economic transactions at issue"); *id.* at 22 ("If Defendants

had not warranted the VCDs were FDA approved . . . then the sale of the VCDs would have been prohibited at each step of the economic transactions at issue.").) The record similarly shows that Plaintiffs are seeking to recover based on Defendants' purported fraud on the FDA. (*See, e.g.*, ECF 2569-3 ¶ 41.5 (Plaintiffs claiming to cite evidence that "ZHP did not disclose its knowledge of and about the NDMA contamination of its valsartan to the FDA at the time of the July 27, 2017 email"); ECF 2569-1 at 17 (Plaintiffs claiming that "Teva did not inform the FDA about the NDMA contamination within the timeframe mandated by regulation and Teva's own SOP").)

In short, Plaintiffs' lawsuit does not "parallel or reinforce the agency's efforts," *Lofton*, 672 F.3d at 377; rather, Plaintiffs' misrepresentation "claims exist solely by virtue of the FDCA disclosure requirements," and are therefore preempted, *Buckman*, 531 U.S. at 352-53.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of Defendants.

Dated: June 27, 2025

Respectfully submitted,

/s/ Jessica Davidson

KIRKLAND & ELLIS LLP
Jessica Davidson, P.C. (*pro hac vice*)
601 Lexington Avenue
New York, NY 10022
Tel: (212) 446-4723
jessica.davidson@kirkland.com

Allison M. Brown, P.C.
2005 Market Street, Suite 1000
Philadelphia, PA 19103
Tel: (215) 268-5000
alli.brown@kirkland.com

Nina R. Rose, P.C. (*pro hac vice*)
Jordan M. Schwartz (*pro hac vice*)
1301 Pennsylvania Avenue
Washington, D.C. 20004
Tel: (202) 389-3394
nina.rose@kirkland.com
jordan.schwartz@kirkland.com

Attorneys for Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Solco Healthcare U.S., LLC, and Prinston Pharmaceutical Inc.

GREENBERG TRAURIG, LLP
Steven M. Harkins
Lori G. Cohen, Esq.
Victoria Davis Lockard
Terminus 200
3333 Piedmont Rd., NE, Suite 2500
Atlanta, Georgia 30305
Tel: (678) 553-2385
harkinss@gtlaw.com
cohenl@gtlaw.com

lockardv@gtlaw.com

Gregory E. Ostfeld
Tiffany M. Andras
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601
Tel: (312) 456-8400
ostfeldg@gtlaw.com
andrast@gtlaw.com

Attorneys for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc.

KIRKLAND & ELLIS LLP
Devora W. Allon, P.C.
Alexia R. Brancato, P.C.
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
devora.allon@kirkland.com
alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 27, 2025, a true and correct copy of the foregoing document was served upon counsel of record via operation of the Court's electronic filing system.

Dated: June 27, 2025

Respectfully submitted,

/s/ Jessica Davidson

Jessica Davidson, P.C. (*pro hac vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Tel: (212) 446-4723
jessica.davidson@kirkland.com